

	Description
Function	Analytical Project Leader in New Biological Entities (NBE)
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne hr@acimmune.com
Percentage	100 % - available immediately
Reporting Line	Analytical Development and Quality Control
Overview	<p>AC Immune is a clinical-stage Swiss Biotech Company focused on the development of innovative therapeutics and diagnostics for Alzheimer's and other neurodegenerative diseases.</p> <p>AC Immune is seeking a highly qualified Analytical Project Leader to support its CMC product development programs.</p> <p>The candidate must possess a strong scientific background in Analytical Chemistry and must have drug development experience, preferably for monoclonal antibodies and within a CMC and QC setting. He/she must have a clear record of scientific accomplishments and ability to interact across functions within a dynamic matrix organization.</p>
Job description	<p>Analytical Project Leader (NBE) Responsibilities:</p> <p>Lead and manage the analytical-related activities (release, stability, characterization, method development/transfer/validation, specification setting, etc) of Drug Products, APIs and raw materials</p> <ul style="list-style-type: none"> • Coordinate and/or perform the analytical-related activities to support Research and Manufacturing in house and at third parties • Depending on project needs and growth, supervise and coach technician(s) • Prepare, review and evaluate internal and third party scientific and technical protocols and reports as well as QC documents, including data consolidation and analysis • Support Analytical Development and QC department in designing and monitoring the strategy, timelines and budget for assigned projects • Support QA, Regulatory and Manufacturing departments in monitoring and evaluation of quality-related events (e.g. OOS, deviations, change controls) • Ensure high quality analytical documentation for submission to Health Authorities • Present data at international scientific conferences and publishing in scientific peer-reviewed journals
Qualifications	<p>The candidate should have the following qualifications:</p> <ul style="list-style-type: none"> • Ph.D. or equivalent in Analytical Chemistry, Biochemistry, Biology or a related discipline applied to large molecules • Analytical, QC or research related expertise (≥ 5 years) in the pharmaceutical/biotech field of New Biological Entities, preferably interacting within multi-disciplinary teams • Successful industrial experience in physico-chemical methods, protein characterization and analytical project management for monoclonal antibodies • Excellent knowledge and hand-on expertise on a wide variety of physicochemical and bioanalytical techniques (eg HPLC/UPLC, LC-MS, SEC, electrophoresis, MALDI, IR, CD, ELISA, etc) • Strong understanding of CMC analytical strategy for NBE (e.g. antibodies, therapeutic proteins and protein conjugates) at all clinical phases is an asset

Analytical Project Leader (NBE)

	<ul style="list-style-type: none">• Experience in Regulatory Affairs and Quality applied to analytics (i.e. Ph.Eur./USP monographs and chapters, and ICH/FDA guidelines) is a plus• High level of analytical troubleshooting and problem solving skills• Proactive and flexible team player, with ability to manage parallel activities, within different projects in a fast-paced environment• Advanced communication (including scientific/technical) skills, both verbal and written• Fluency in English; French and a third language are assets
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